

## **Pharmacy Student Rotation Objectives**

### **FDA/CDER/OND/OODP Division of Biologic Products (DBOP)**

Goals: The purpose of this rotation is to familiarize the pharmacy student with the role of the Food and Drug Administration (FDA) during a drug or biologic product's development and approval lifecycle. The DBOP pharmacy student rotation will emphasize regulation of new drug or biologic products and review of new drug submissions. The DBOP pharmacy student will gain professional experience from within the FDA's Office of New Drugs, and assist with the implementation of drug or biologic product labeling initiatives that provide critical drug information to health care professionals.

*I. Learning Objectives:* Upon completion of this rotation the student will be able to:

- A. Describe the role of the FDA during the regulatory management of a new drug or biologic product.
- B. Understand the drug review processes from initial submission to the time of approval, termination or withdrawal.
- C. Apply knowledge that encompasses a mastery of FDA regulations, legislation, and administrative procedures involved in the drug approval process.
- D. Discuss and identify the different types of FDA submissions in Investigational New Drug Applications (IND), Biologic License Applications (BLA), and New Drug Applications (NDA).
- E. Understand regulatory requirements for drug approvals and the role of FDA guidance for industry documents to aid in the development of therapeutic products.

*II. Student Requirements:* The student will be exposed to a variety of regulatory management initiatives and electronic resources used during the premarket approval process for drug and biologic products. To meet the learning objectives listed above the student will be expected to:

- A. Research FDA drug regulations, standard operating procedures, and guidance documents to aid in the implementation and understanding of regulatory processes.
- B. Complete regulatory topic review discussions with preceptors.
- C. Give a presentation or conduct a project assigned by preceptors.
- D. Attend student rotations within the Office of the Commissioner and the Center for Drug Evaluation and Research.
- E. Fulfill required student hours.